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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,363	09/07/2006	Shinya Kusuda	Q93058	2292
23373                      7590                      11/24/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER				
CARTER, KINDRA D				
ART UNIT		PAPER NUMBER		
1627				
NOTIFICATION DATE		DELIVERY MODE		
11/24/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com  
PPROCESSING@SUGHRUE.COM  
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### Office Action Summary

**Application No.**

10/567,363

**Applicant(s)**

KUSUDA ET AL.

**Examiner**

KENDRA D. CARTER

**Art Unit**

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 and 16 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group I, claims 1, 2 in part, 3 in part, 7 in part, and 8-13, are drawn to a compound and composition of formula I wherein A, B and D are carbocyclic, and W, X, Y, R<sup>1</sup>, M, X<sup>a</sup>, Y<sup>a</sup> or Z<sup>a</sup> are alkylene groups or that defined in claims 2 or 3.
- II. Group II, claims 2 in part and 4-6, are drawn to a compound of formula IC, wherein A, B or/and D is independently an oxygen or sulfur heterocycle, and X<sup>a</sup> is oxygen or sulfur.
- III. Group III, claim 2 in part, is drawn to a compound of formula IC, wherein A, B or/and D is independently an oxygen or sulfur heterocycle, and X<sup>a</sup> is CO or CONR<sup>2</sup>.
- IV. Group IV, claim 2 in part, is drawn to a compound of formula IC, wherein A, B or/and D is independently a nitrogen heterocycle, and X<sup>a</sup> is CO or CONR<sup>2</sup>.
- V. Group V, claims 2 in part, 4-6 and 7 in part, are drawn to a compound of formula IC, wherein A, B or/and D is independently a nitrogen heterocycle, and X<sup>a</sup> is oxygen or sulfur.

- VI. Group VI, claim 14, is drawn to a method for accelerating evacuation of lipid in a mammal comprising administering an effective amount of the compound of formula I, wherein A, B and D are carbocyclic and W, X and Y are alkylene groups or that defined in claim 3.
- VII. Group VII, claim 14, is drawn to a method for accelerating evacuation of lipid in a mammal comprising administering an effective amount of the compound of formula IC, wherein A, B or/and D is independently an oxygen or sulfur heterocycle, and X<sup>a</sup> is oxygen or sulfur.
- VIII. Group VIII, claim 14, is drawn to a method for accelerating evacuation of lipid in a mammal comprising administering an effective amount of the compound of formula IC, wherein A, B or/and D is independently an oxygen or sulfur heterocycle, and X<sup>a</sup> is CO or CONR<sup>2</sup>.
- IX. Group IX, claim 14, is drawn to a method for accelerating evacuation of lipid in a mammal comprising administering an effective amount of the compound of formula IC, wherein A, B or/and D is independently a nitrogen heterocycle, and X<sup>a</sup> is CO or CONR<sup>2</sup>.
- X. Group X, claim 14, is drawn to a method for accelerating evacuation of lipid in a mammal comprising administering an effective amount of the compound of formula IC, wherein A, B or/and D is independently a nitrogen heterocycle, and X<sup>a</sup> is oxygen or sulfur.
- XI. Group XI, claim 16, is drawn to a method for preventing and/or treating PPAR d-mediated diseases in a mammal comprising administering an effective amount of the compound of formula I, wherein A, B and D are carbocyclic and W, X and Y are alkylene groups or that defined in claim 3.
- XII. Group XII, claim 16, is drawn to a method for preventing and/or treating PPAR d-mediated diseases in a mammal comprising administering an effective amount of the compound of formula IC, wherein A, B or/and D is independently an oxygen or sulfur heterocycle, and X<sup>a</sup> is oxygen or sulfur.

- XIII. Group XIII, claim 16, is drawn to a method for preventing and/or treating PPAR  $\delta$ -mediated diseases in a mammal comprising administering an effective amount of the compound of formula IC, wherein A, B or/and D is independently an oxygen or sulfur heterocycle, and X<sup>a</sup> is CO or CONR<sup>2</sup>.
- XIV. Group XIV, claim 16, is drawn to a method for preventing and/or treating PPAR  $\delta$ -mediated diseases in a mammal comprising administering an effective amount of the compound of formula IC, wherein A, B or/and D is independently a nitrogen heterocycle, and X<sup>a</sup> is CO or CONR<sup>2</sup>.
- XV. Group XV, claim 16, is drawn to a method for preventing and/or treating PPAR  $\delta$ -mediated diseases in a mammal comprising administering an effective amount of the compound of formula IC, wherein A, B or/and D is independently a nitrogen heterocycle, and X<sup>a</sup> is oxygen or sulfur.

The groups of inventions I to V listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Particularly, the groups do not have the same compound.

The groups of inventions VI to X listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Particularly, the groups do not have the same compound.

The groups of inventions XI to XV listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Particularly, the groups do not have the same compound.

The common technical feature in groups I, VI and XI is the compound. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

In this case, Pelcman et al. (WO 02/43648 A2) teach the Applicant's compound as formula I, wherein X is  $\text{CH}_2$ ,  $\text{R}^6$  is a cycloalkyl and  $\text{R}^1$  is COOH (see page 3 and 4).

As a result, no special technical features exist among groups I, VI and XI because they fail to make a contribution over the prior art with respect to novelty and inventive step. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

The common technical feature in groups II, VII and XII is the compound. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

In this case, Pelcman et al. (WO 02/43648 A2) teach the Applicant's compound as formula I, wherein X is CH<sup>2</sup>, R<sup>6</sup> is a heterocycloalkyl or heteroaryl and R<sup>1</sup> is COOH (see page 3 and 4). Heteroaryl refers to a mono-bi- or tricyclic ring system having from 5 to 10 ring atoms, in which at least one ring is aromatic, and in which one or more of the ring atoms are other than carbon, such as nitrogen, sulfur, oxygen and selenium (see page 13, second paragraph).

As a result, no special technical features exist among groups II, VII and XII because they fail to make a contribution over the prior art with respect to novelty and inventive step. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

The common technical feature in groups III, VIII and XIII is the compound. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

In this case, Duan et al. (US 6,495,565) teach the Applicant's compound as compound 114, wherein Z and Z<sup>a</sup> are either a C<sub>3-13</sub> carbocycle or a 5-14 membered heterocycle; U<sup>a</sup> is an oxygen or carbonyl; X<sup>a</sup> is a C<sub>1-10</sub> alkylene; and Y<sup>a</sup> is absent (see column 62, compound 114 and column 4).

As a result, no special technical features exist among groups III, VIII and XIII because they fail to make a contribution over the prior art with respect to novelty and inventive step. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

The common technical feature in groups IV, IX and XIV is the compound. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

In this case, Duan et al. (US 6,495,565) teach the Applicant's compound as compound 82, wherein Z and Z<sup>a</sup> are either a C<sub>3-13</sub> carbocycle or a 5-14 membered heterocycle; U<sup>a</sup> is an oxygen or carbonyl; X<sup>a</sup> is a C<sub>1-10</sub> alkylene; and Y<sup>a</sup> is absent (see column 58, compound 82 and column 4).

As a result, no special technical features exist among groups IV, IX and XIV because they fail to make a contribution over the prior art with respect to novelty and inventive step. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

The common technical feature in groups V, X and XV is the compound. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

In this case, Pelcman et al. (WO 02/43648 A2) teach the Applicant's compound as formula I, wherein X is CH<sup>2</sup>, R<sup>6</sup> is a heterocycloalkyl or heteroaryl and R<sup>1</sup> is COOH (see page 3 and 4). Heteroaryl refers to a mono-bi- or tricyclic ring system having from 5 to 10 ring atoms, in which at least one ring is aromatic, and in which one or more of the ring atoms are other than carbon, such as nitrogen, sulfur, oxygen and selenium (see page 13, second paragraph).

As a result, no special technical features exist among groups V, X and XV because they fail to make a contribution over the prior art with respect to novelty and inventive step. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- 1) a compound for each Group; and
- 2) a PPAR  $\delta$ -mediated disease in claim 16.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, all claims are generic.

#### REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

The special technical feature (i.e. the compound) is not the same for Groups I to V. As a result, no special technical features exist among the different groups. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

The following cluster of Groups have the same compounds and thus have the same special technical feature: 1) Groups I, VI and XI; 2) Groups II, VII, and XII; 3) Groups III, VIII and XIII; 4) Groups IV, IX and XIV; and 5) Groups V, X and XV.

#### WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

In this case the application calls for a product and three different methods of use (i.e. a composition, and two different methods).

Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely

traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kendra D Carter/  
Examiner, Art Unit 1627

/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1627